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(71) Applicant *(for all designated States except US)*: SPINAL DYNAMICS CORPORATION [US/US]; Suite 110, 9655 SE 36th Street, Mercer Island, WA 98040-3732 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: BRYAN, Vincent [US/US]; Suite 110, 9655 SE 36th Street, Mercer Island, WA 98040-3732 (US). KUNZLER, Alex [US/US]; 50340 Spyglass Hill Drive, La Quinta, CA 92253 (US).

(74) Agent: PARKHURST, Todd, S.; Hill & Simpson, Sears Tower, 85th floor, 233 South Wacker Drive, Chicago, IL 60606 (US).

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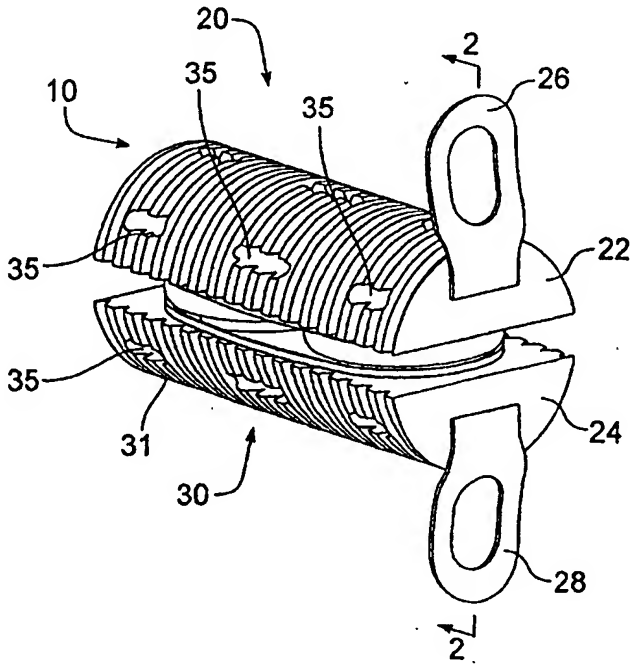
(54) Title: THREADED CYLINDRICAL MULTIDISCOID SINGLE OR MULTIPLE ARRAY DISC PROSTHESIS

(57) Abstract

A small profile, cylindrically shaped prosthetic disc device (10) is provided. The device housing is comprised of two longitudinally split hollow halves (20, 30), between which are contained multiple discoid shaped resilient bodies (41, 42) which may be of a polymeric type, or they may contain hydrogel. These bodies may lie in concave surfaces (51, 52) located on the interior of each side of the split cylindrical housing. The housing halves (20, 30) even under maximum physiological loads, do not contact one another directly. Threads on the exterior surface of the cylindrical housing facilitates insertion and retention in the prepared bone opening.



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SPECIFICATION

TITLE

THREADED CYLINDRICAL MULTIDISCOID SINGLE OR MULTIPLE ARRAY DISC PROSTHESIS

This invention relates to the design and use of a unique disc prosthesis for the lumbar, thoracic and cervical spine.

U.S. Patent 5,674,296 is incorporated by reference.

BACKGROUND OF THE INVENTION

Degenerative disc disease including disc herniation may produce disabling symptoms of local pain, radiculopathy or myelopathy in an otherwise clinically stable spine, which proves to be unresponsive to non-surgical treatment. Several surgical treatments are available to address the symptoms of degenerative disc disease when non-invasive therapies are not effective. These surgical treatments include decompression, discectomy and fusion. These treatments, and in particular the discectomy and fusion procedures, provide relief of clinical symptoms but they do not restore normal or near normal range of motion or cushioning to the affected functional spinal unit (FSU). This can result in acceleration of the degenerative process in spinal discs adjacent to the original surgical operation site. This degenerative process can, in turn, require additional surgical intervention.

Open surgery and endoscopic techniques are often used to provide access to the targeted intervertebral disc space. Posterior, postero-lateral, and anterior approaches allow placement of instrumentation to facilitate exposure of the degenerated disc and the insertion of bone grafts or fusion cages to accomplish bony fusion.

Because of anatomical structure considerations and instrument size restrictions associated with minimally invasive surgical techniques in the anterior spine, the insertion of a functional disc prosthesis equal in size to the natural disc creates risks due to mechanical interferences with critical vascular structures and may prevent safe insertion of the prosthesis.

A functional disc prosthesis which provides for a full range of motion of the FSU and for cushioning between two adjacent vertebrae while maintaining stability,

intervertebral body spacing and lordosis, is desirable, more specifically it is an object of the invention to provide a disc prosthesis having a small or narrow profile. The novel exemplary prosthesis is cylindrical in exterior shape, comprised of two longitudinally split halves. Each housing half is separated from the other at all times by disk shaped resilient bodies contained therein, and is strong enough to support the loads to which it shall be subjected during the activities of daily living. The housing contains multiple concave articulation recesses capable of mating with the discoid resilient bodies placed therebetween. The discoid bodies are of smaller diameter than the natural disc they replace, and are positioned in series in the shells or articulation recesses contained in the interior of the cylindrical housing. The cylindrical housing is threaded on its exterior for ease of introduction into, and mechanical stability in, a prepared space in the opposing vertebrae of the FSU. The housing is configured to fit the restrictions imposed by the limited anatomical space available for the surgical placement of the implant, and is small so as to utilize implantation procedures and instrumentation such as those used in an endoscopic procedure.

It is a further object of the invention to provide cylindrical housings of differing size, and resilient bodies contained within, so that when the cylindrically shaped prostheses units are used in parallel, they may facilitate proper positioning of opposing vertebrae.

Another object is to obviate the need for a second surgical site for bone graft harvesting.

And it is a further object of the invention to provide a sheath so as to completely surrounded and enclose the space occupied by the resilient bodies between the two cylindrical housing halves.

Still another object of the invention is to provide a disc prosthesis which will permit motion between the housing halves.

A further object of the intention is to provide a disc prosthesis which will provide for cushioning between the housing halves.

It is a still further object of the invention to provide a disc prosthesis which may be used alone or in parallel array with similar prostheses.

Other objects and advantages of the invention will become apparent to those skilled in the art upon reading the following detailed description and upon reference to the drawings. Throughout the drawings, like reference numerals refer to like parts.

DESCRIPTION OF THE DRAWINGS

Figure 1 is an isometric view of the novel disc prosthesis.

Figure 2 is a sectional view taken substantially in the plane of line 2-2 in figure 1.

Figure 3 is a sectional view taken substantially in the plane of line 3-3 in figure 2.

Figure 4 is an isometric view similar to figure 1 but showing an alternate embodiment of the invention.

Figure 5 is a sectional view taken substantially in the plane of line 5-5 in figure 4.

Figure 6 is a sectional view taken substantially in the plane of line 6-6 in figure 5.

Figure 7 is an isometric view of a lower half housing of the invention.

Figure 8 is a top plan view of the lower half housing shown in figure 7.

Figure 9 is a sectional view taken substantially in the plane of line 9-9 in figure 8.

Figure 10 is a sectional view taken substantially in the plane of line 10-10 in figure 9.

Figure 11 is a top plan view of a lower half housing similar to figure 8 but showing and alternate embodiment of the invention.

Figure 12 is a sectional view similar to figure 9 but taken substantially in the plane of line 12 – 12 in figure 11.

Figure 13 is an isometric view of the lower half housing shown in figures 11 and 12.

Figure 14 is a sectional view taken substantially in the plane of line 14 – 14 in figure 12.

While the invention will be described in connection with a preferred embodiment,

it will be understood that it is not intended to limit the invention to this embodiment. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

To accomplish the objectives set out above, the novel exemplary disc prosthesis 10 includes, as shown in figures 1 and 4, a cylindrical housing 20. The housing 20 includes an upper half housing 22 and a lower half housing 24. In the embodiment showed in figure 1, an upper fixator wing 26 is welded or otherwise associated with the upper half housing 22, and a lower fixator wing 28 is similarly welded or otherwise associated with the lower half housing 24. These wings 26, 28 can be used to stabilize the prosthesis to bone, as suggested in U.S. Patent 5,674,296. The wings 26, 28 can be omitted, as suggested in figures 4 - 14.

As particularly shown in figures 2, 3, 5 and 6, a plurality of resilient, viscoelastic discs 41, 42 are interposed between the upper half housing 22 and the lower half housing 24 to maintain the housing halves separate from one another and to provide for a defined range of motion. Alternatively, the discs 41, 42 may be made of a suitable hydrogel. If desired, generally conical bosses or posts 29 can fit into recesses 33 formed in the discs 41, 42 to provide stability and limitation against excessive motion.

The housing 20 has an exterior surface 30 which bears a screw thread shape 31. This screw thread shape 31 is continuous, and is contiguous from housing half 22 to housing half 24 so that the disc prosthesis can be screwed into a pre-tapped intervertebral space hole formed within between two adjacent vertebrae as, for example, in the human spine. If desired, recesses 35 can be formed to permit bone ingrowth and further stabilization of the device. The housing 20 shape can be that of a right cylinder or it can be conical.

In accordance with one aspect of the invention, this small or thin profile prosthesis 10 can be created by placing more than one ovoid resilient prosthetic discs 41, 42 within a cylindrical housing 20 of metal, ceramic or polymeric material (the housing 20 having been separated into two halves 22, 24 longitudinally). This small device 10 can be implanted in the spine through a small surgical opening. One device 20 containing two or more discs 41, 42 may be used, or by placing two such devices 20 in parallel, each

containing two or more ovoid discs in series, a full range of motion of the functional spinal unit (FSU) can be achieved. If the discoid material possesses resilient, viscoelastic properties, with the housing being split or otherwise open on its sides with the internally placed ovoid discs maintaining the separation of the upper and lower housing members, a cushioning effect may also be realized. If desired, a flexible sheath or seal can be attached to the housing halves, as by a retaining wire or band, as suggested in U.S. Patent 5,674,296.

As suggested in figures 7 - 10, each ovoid disc 41, 42 may be surrounded by a concave surface 51, 52 formed or contained within the housing, and contoured to accept the upper and lower surface shape of each of the ovoid discs 41, 42 so that the housing 20 comprising the two or more halves or paired shells 23, 24 may slide and/or rotate over the surface of the discs 41,42 to provide for joint space separation and motion.

As suggested in figures 11-14, a single recess 61 can be provided to accommodate both discs 41, 42. If desired, posts 29 can be provided to limit disc - housing half relative motion.

As noted above, the exterior surface of the split housing 20 has a threaded formation so that it may be screwed into a pre-tapped hole of appropriate size at an intervertebral disc space. When properly screwed into place, the upper half of the threaded housing engages the cephalad vertebral bone inferior end plate and the other half 24 of the threaded housing engages the opposing superior end plate of the caudal vertebral bone when fully inserted. The ovoid discs 41, 42 and their respective concave surfaces in any one housing unit may be of differing size so as to allow for appropriate spinal column curvature, especially when inserted in the anterior/ posterior direction, or they may be the same size in any one housing but differ from the size of the discs in the second housing placed in parallel when inserted from a lateral direction.

The device may be inserted via open or minimally invasive techniques including endoscopy, or by a variety of known surgical approaches where adequate anatomical space is available. Though the prosthesis is inserted as a single threaded cylindrical unit, its final position is such that one half of the housing is left exclusively in contact with the end plate of one vertebral body and the other in the exclusive contact of the opposing vertebral body end plate. The discoid vertebral bodies between the cylindrical housing

halves contain two or more concave surfaces, allow movement by providing for sliding and rotating in multiple directions and cushioning in response to physiological loads placed upon them. When cylinders of different size are at used in parallel, intervertebral spacing can be varied to achieve desired vertebrae positional relationships.

I CLAIM:

1. A disc prosthesis comprising, in combination, a cylindrical housing, the housing including an upper half and a lower half and a plurality of resilient, viscoelastic discs interposed between the upper half housing and the lower half housing to maintain the housing halves separate from one another.

2. A disc prosthesis according to claim 1 wherein said discs are ovoid in shape.

3. A disc prosthesis according to claim 1 wherein each disc is partly surrounded by a concave surface formed within said housing.

4. A disc prosthesis according to claim 1 wherein said housing has a threaded exterior surface bearing a screw thread shape.

5. A disc prosthesis according to claim 4 wherein said screw thread is continuous, and is contiguous from housing half to housing half so that the disc prosthesis can be screwed into a pre-tapped intervertebral space hole.

6. A disc prosthesis according to claim 1 wherein recesses are defined in said housing to permit bone ingrowth.

7. A disc prosthesis according to claim 1 including a wing member attached to each of the upper and the lower half housing members, the wings permitting the housing halves to be affixed to spinal vertebrae.

8. A disc prosthesis affixed within a human spine, the prosthesis comprising an upper half housing engaging the cephalad vertebral bone inferior end plate; a lower half housing engaging the caudal vertebral bone superior and plate; and a plurality of separate, resilient discs interposed between the housing halves.

9. A disc prosthesis according to claim 8 wherein each disc is partly surrounded by a concave surface formed within one of said housing halves.

10. A disc prosthesis according to claim 8 wherein each housing half has a threaded exterior surface.

11. A disc prosthesis comprising, in combination, a hollow cylindrical housing, the housing including two separate halves and at least one prosthetic disc located between the two housing halves.

12. A disc prosthesis according to claim 11 in which each housing half is at least partly defined, in its interior, by a concave surface.

13. A plurality of disc prostheses located within a human spine , each prosthesis comprising an upper half housing engaging a cephalad bone inferior end plate; a lower half housing engaging a caudal vertebral bone superior end plate; and at least one resilient disc interposed between each of the housing halves.

14. A plurality of disc prostheses according to claim 13, each prosthesis having a threaded exterior surface.

15. A plurality of disc prostheses according to claim 14 wherein each prosthesis has recesses defined in its exterior surface to permit bone ingrowth.

16. A viscoelastic prosthetic disc for use in a human spinal implant, the disc having viscoelastic properties similar to the natural biological disc found in the human spine, the prosthetic disc having convex external surfaces for sliding engagement with concave surfaces formed on the interior of rigid upper and lower half housings

17. The disc of claim 16 wherein said disc has a relatively soft and resilient interior and a relatively hard and durable exterior.

18. A disc prosthesis comprising, in combination, a housing, the housing having an exterior surface defining a general continuous thread formation, the housing including at least two rigid, confronting and complimentary parts, the prosthesis further comprising at least one resilient, viscoelectric disc interposed between the housing parts to maintain the housing parts separate from one another but to provide cushioning between the housing parts and to permit limited motion from between the housing parts.

19. A disc prosthesis according to claim 18 wherein the housing thread is adapted to engage the bone of adjacent vertebral bodies.

20. A disc prosthesis according to claim 18 including a sheath attached to said housing halves.

21. A disc prosthesis according to claim 18 including a plurality of nuclei of different sizes.

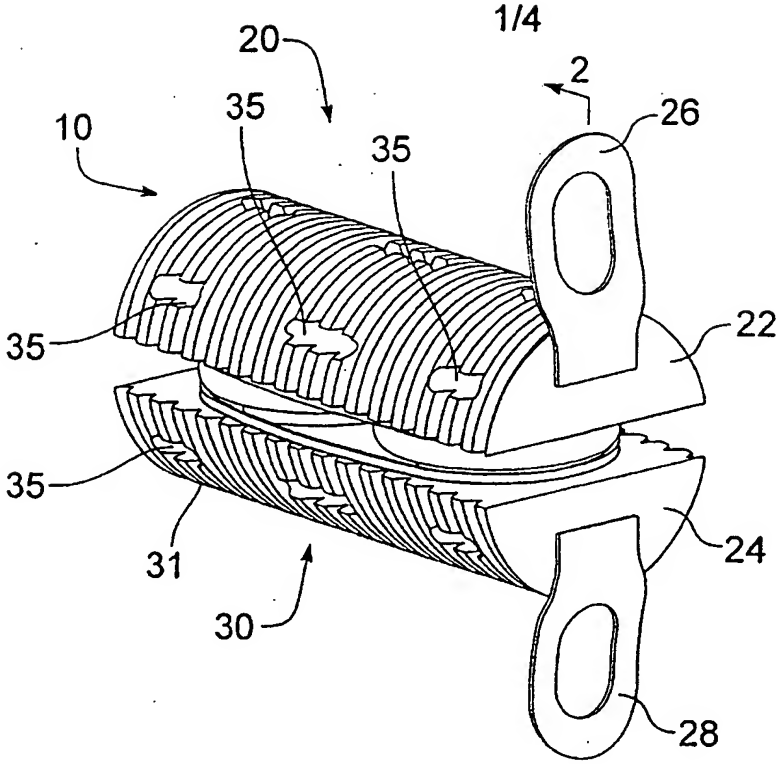


FIG.1

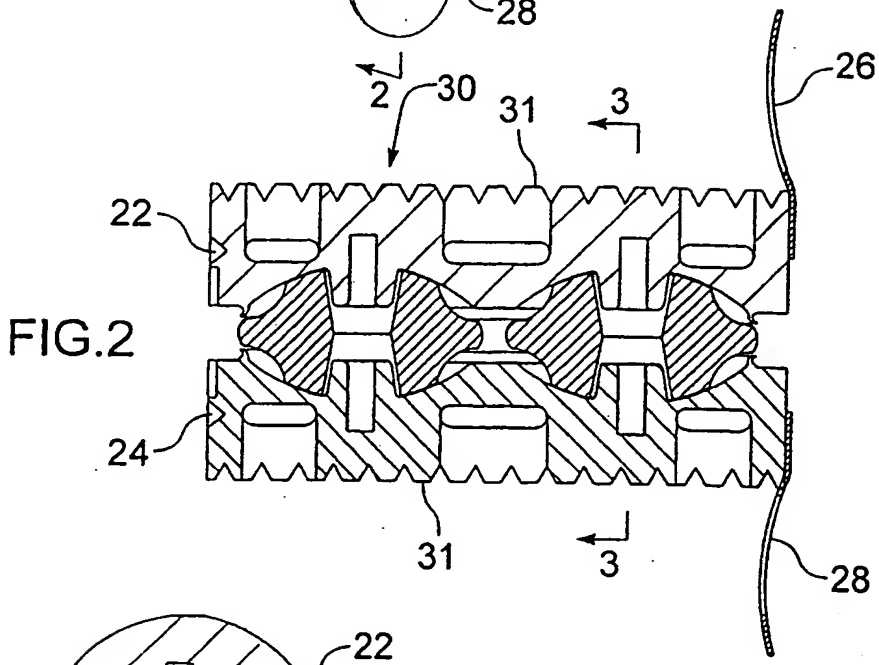


FIG.2

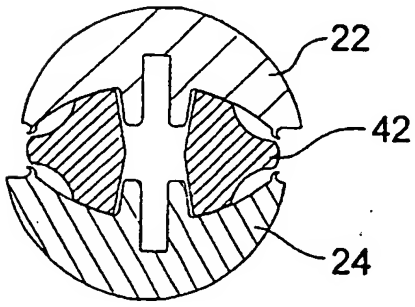


FIG.3

FIG.5

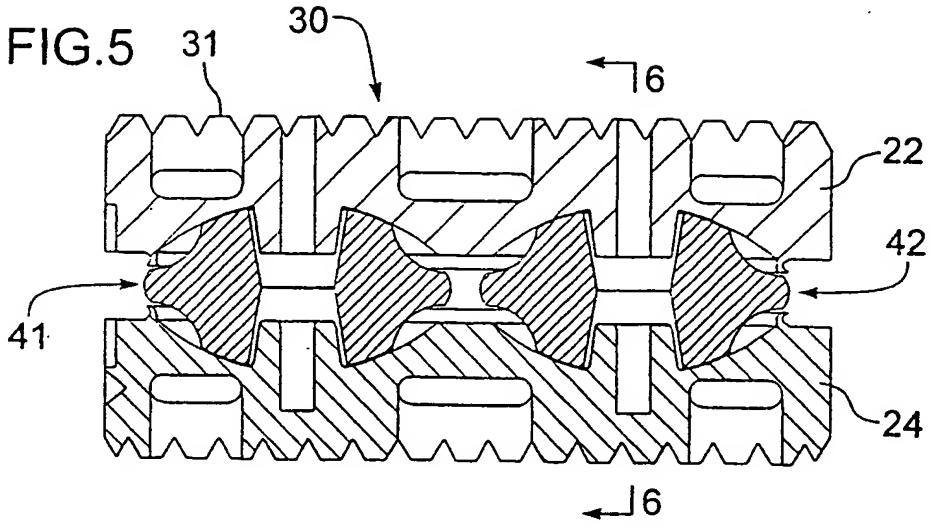


FIG.4

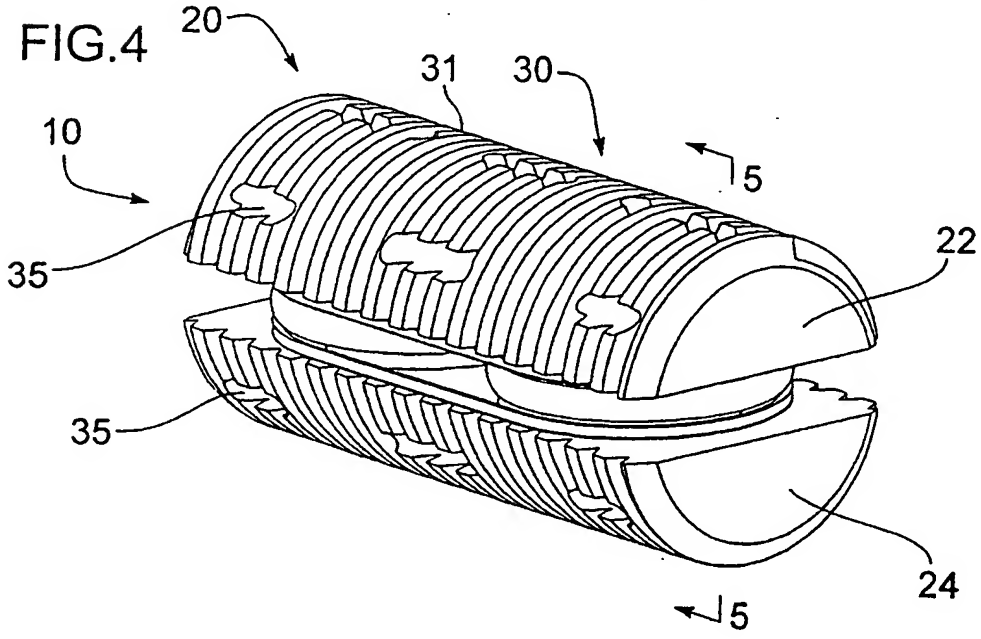


FIG.6

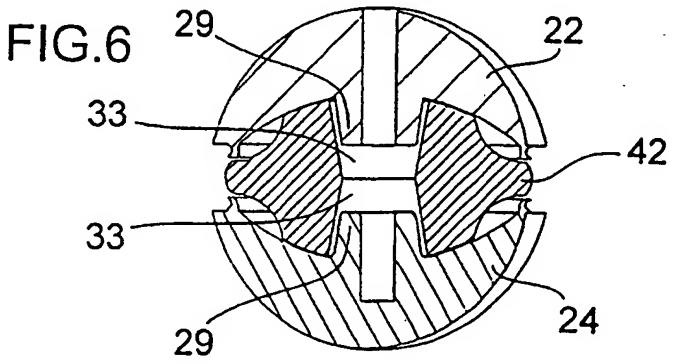
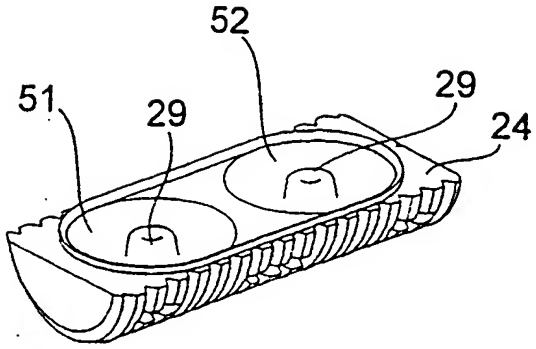


FIG.7



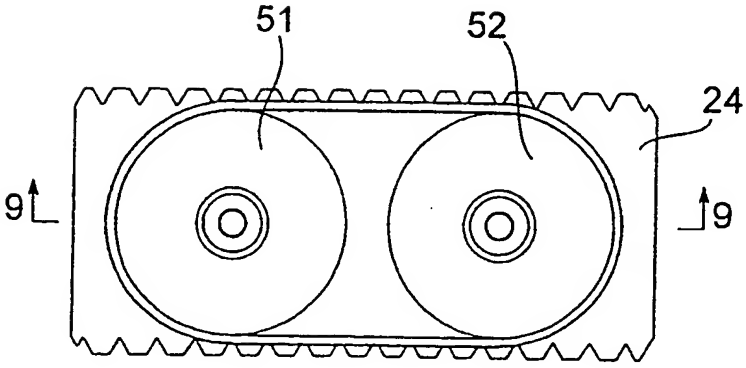
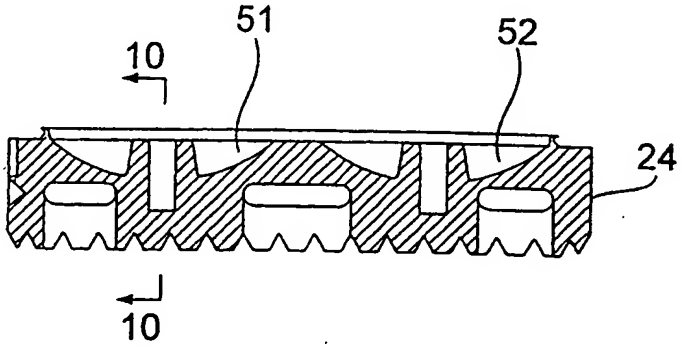


FIG.8

FIG.9



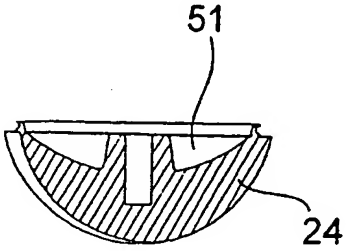
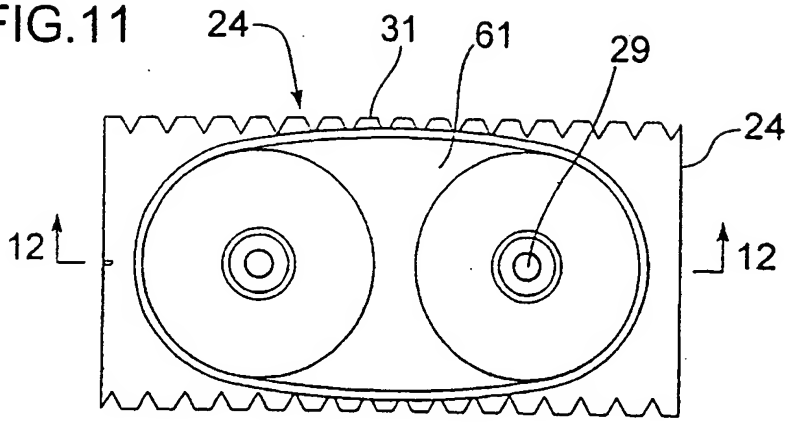


FIG.10

FIG.11



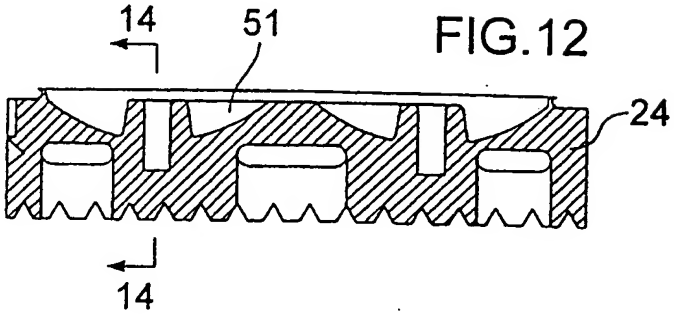


FIG.12

FIG.13

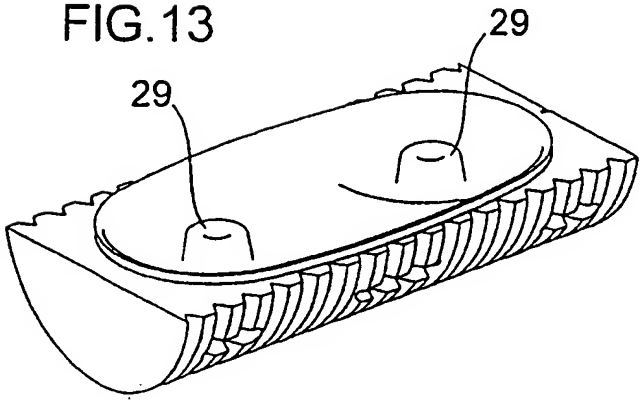
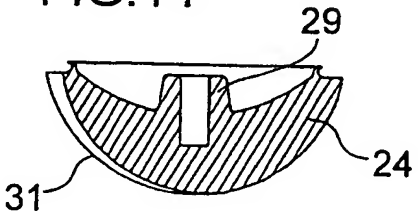


FIG.14



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/16648

A. CLASSIFICATION OF SUBJECT MATTER
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US CL : 623/17
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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -----E Y	US 5,928,284 A (MEHDIZADEH) 27 July 27 1999, Figs. 1 and 5 (the wings).	11, 13-19 --- 1, 4-7
X	US 5,674,294 A (BAINVILLE et al) 07 October 1997, Fig. 2.	18, 21
X	US 5,674,296 A (BRYAN et al.) 07 October 1997, Fig. 3.	18, 20
X -----P Y	US 5,824,093 A (RAY et al.) 20 October 1998, Figs. 11a and 11b.	8 --- 9, 10

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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